UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,320	01/12/2001	Reinhard Walter	LE-A-32-842	3404

7590 05/27/2009

RICHARD S BULLITT
BAYER CORPORATION
36 COLUMBIA ROAD P O BOX 1910
MORRISTOWN, NJ 07962-1910

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/700,320	WALTER ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A new Examiner has been assigned to the application. In order to be clear, the indicated allowability of claims 8-15 is withdrawn in view of the newly discovered reference(s) to Robinson et al. US 6071539 and Hoff et al. US 3872227. Rejections based on the newly cited reference(s) follow. This action is non-final.

Withdrawn rejections:

Applicant's amendments and arguments filed 7/21/04 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 8-15 were rejected under 35 USC 112 first paragraph because the word substrate is not verbatim in the specification as filed. Applicant's arguments are persuasive and this rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Claim 8 introduces new matter as the claims recite the limitation: "substantially throughout" and "substantial constituent" in the amendment filed on 9/24/02. There is no support in the specification for this limitation and they represent new concepts not previously presented. These limitations were not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Response to arguments:

In the response filed on 6/9/03 regarding the rejection of claims 8-10 under 35 USC 112 first paragraph, Applicant asserted that "substantially throughout" is intended to convey that one or both of the effervescent couple should be sufficiently dispersed in the substrate to stabilize the medicament and "substantial constituent" is intended to convey that the ingredient should comprise a sufficient amount of substrate to stabilize the medicament.

These arguments are not persuasive because the specification lacks some standard for measuring the degree intended which is particularly important when even Applicant admits that the melts are not homogenous and may only partially melt and some may not comprise a melted substrate at all (see remarks filed on 6/9/03, page 7).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 introduces new matter (the amendment filed on 6/9/03) as the claims recite the limitation: "substantially dispersed". There is no support in the specification for this limitation and it represents a new concept not previously presented. This limitation was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites: "substantially throughout" and "substantial constituent". This is indefinite because the specification lacks some standard for measuring the degree intended. Claims 9 and 10 are rejected as being indefinite because they are dependent on an indefinite base claim.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites: "substantially dispersed". This is indefinite because the specification lacks some standard for measuring the degree intended. Claims 11-15 are rejected as being indefinite because they are dependent on an indefinite base claim.

Claims 8-15 will be examined as they read on the presence of the components recited.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 recites the limitation "said ancillary substance" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "said ancillary substance" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoff et al. US 3872227 or in the alternative is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff et al. US 3872227.

Hoff et al. disclose formulations for oral administration (Abstract and claims 1-20). Hoff et al. disclose an effervescent tablet in Example 7:

EXAMPLE 7 — Phenoxymethylpenicillin Effervescent Tablets, 600,000 U each

32 parts of citric acid, 38 parts of sodium bicarbonate, 4.1 parts of sugar, 16 parts of glycine and 1.6 parts of serine are mixed and finely powdered by means of a mill. This mixture is subsequently uniformly moistened, in a kneader, with an alcoholic solution of 0.2 parts of sodium saccharin and dried in a fluidized bed.

The sieved granules are mixed with 7.1 parts of phenoxymethylpenicillin (either as the acid, or employed as the potassium salt, corresponding to 7.8 parts), 0.5 parts of tutti-frutti dry flavoring and 0.5 parts of sodium benzoate.

Effervescent tablets weighing 5.0 g each are prepared from this mixture and when dissolved in water give an aromatic, pleasant-tasting phenoxymethylpenicillin solution.

As is clearly disclosed by Hoff et al., an acidic component (citric acid), a CO2 donor (sodium bicarbonate), sugar (fusible sugar), and sugar substitute (sodium saccharin) are mixed and finely powdered to produce effervescent tablets. Hoff et al. teach using maltose, mannitol, and sorbitol in the composition (column 2, lines 32-36 and column 3, lines 19-25). In the absence of evidence to the contrary, the 'at least one ingredient' is present in an amount sufficient to stabilize at least one of the CO2 donor and acidic component and since the ingredients are mixed then it is the position of the Examiner that the CO2 donor and acidic component are dispersed substantially throughout the substrate which has the ingredient as a substantial constituent. With regards to the limitation of "a structure formed by melting said substrate…", it is the position of the Examiner that this reads on a product by process. Please note that in product-by-process claims, "once a product appearing to be substantially identical is

found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' stabilized medicament differs and, if so, to what extent, from that of the discussed reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Leslie et al. GB 2307857.

Comment: A rejection over this prior art was previously made 6/21/02 and was erroneously withdrawn.

Leslie et al. disclose effervescent tablets (Abstract and claims 1-5). Leslie et al. disclose using a binder that melts or softens below 150 C such as polyethylene glycol (page 2 and 3). Leslie et al. disclose in Example 3 on page 4 the instantly claimed composition:

EXAMPLE 3

Tablets were manufactured containing the following ingredients:-

	mg
Tramadol HCl	50.0
Citric acid anhydrous Ph. Eur.	495.0
Polyethylene glycol 6000 Ph. Eur.	100.0
Saccharin sodium Ph. Eur.	2.5
Sodium hydrogen carbonate Ph. Eur.	581.0
Sodium carbonate anhydrous B.P.C.	40.5

The ingredients were blended in a mixer/granulator equipped with heating facility (heated jacket and/or microwave heater). The temperature was increased to about 60°C whilst mixing until granulation occured. Then the mixture was cooled and if necessary classified by passing through a suitable screen/mill. The resulting granules were compressed into tablets.

In the absence of evidence to the contrary, the 'at least one ingredient' (saccharin; a sugar substitute) is present in an amount sufficient to stabilize at least one of the CO2 donor and acidic component and since the ingredients are mixed then it is the position of the Examiner that the CO2 donor and acidic component are dispersed substantially throughout the substrate (polyethylene glycol 6000) which has the ingredient as a substantial constituent. Therefore, instant claims 8-10 are anticipated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. US 6071539.

Robinson et al. disclose effervescent granules and thermal heat methods of preparing them comprising an acidic agent, a **hot-melt** extrudable binder capable of forming a eutectic mixture (solid solution) with the acidic agent and active agents (Abstract; tables 1-4; column 13, lines 43-45) and claims 1-16). As can be clearly seen in Table 4 below (with Examiner added emphasis),

TABLE 4

Drug-Containing Hot-Melt Extruded Effervescent Formulations

Ibuprofen	50	50	0	0	0	30
Chlorpheniramine Maleate	0	0	5	5	0	5
Pseudoephridine HCl	0	0	0	25	20	
AcDiSol	5	5	0	0	5	5
Microcrystalline Cellulose	20	10	32	20		5
Na Bicarbonate	13	13	15	18	20	15
Citric Acid	12	12	14	15	18	13
PEG 3350	0	10	14	12	10	12
Crosslinked PVP	0	0	5	3	3	3
Explotab	0	0	0	2		2
Mannitol	0	0	5		9	
Xylitol	0	0	10		15	10

formulations with an acidic component (citric acid), a CO2 donor (bicarbonate), a pharmaceutically active substance (ibuprofen) and at least one ingredient that is a sugar alcohol (xylitol). The Examiner notes that Applicant discloses xylitol as a preferred sugar alcohol for use in the invention (page 4, lines 10-11 of the instant specification) which would inherently have the melting points claimed by Applicant. The mixtures are taught by Robinson et al. to be **hot melt extruded blended mixtures** which would inherently read on a structure formed by melting the substrate and re-solidifying the substrate that has the acidic ingredient substantially dispersed throughout the substrate and a substrate that has the ingredient as a substantial constituent. Therefore, instant claims 8-10 are anticipated.

The temperature of the hot melt extrusion will not exceed 150 C which reads on instant claims 12 and 13 (column 14, lines 1-5). Tablets are disclosed which reads on instant claim 15 (examples 3-9, for example). The rate of effervescence can be controlled by varying the hot-melt extrudable binder which can be xylitol or by the relative amounts of ingredients (column 6, line 32-column 7, line 23). Robinson et al. teach grinding the dried granulation which reads on comminution after cooling of instant claim 14 (column 22, lines 24-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. US 6071539.

Applicant claims a process for producing a stabilized medicament, said stabilized medicament comprising: (A) an effervescent system comprising: (i) a CO2 donor, and (ii) an acidic component; (B) a pharmaceutically active substance, and (C) at least one ingredient selected from the group consisting of fusible sugars, sugar alcohols, and sugar substitutes, wherein said process comprises the steps of:

(a) at least partially melting said ingredient,

(b) mixing at least one of said CO2 donor and said acidic component with said at least partially melted ingredient wherein said ingredient is present in an amount sufficient to stabilize said at least one of said CO2 donor and said acidic component to form an at least partially molten blend in which said at least one of said CO2 donor and said acidic component is substantially dispersed,

(c) cooling said at least partially molten blend,

(d) combining said cooled at least partially molten blend, said pharmaceutically active substance and any remaining portion of said effervescent system and

(e) forming said stabilized medicament.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Robinson et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Robinson et al. is that Robinson et al. do not expressly teach the order of steps (a)-(e) as instantly claimed.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Robinson by:

(a) at least partially melting said ingredient,

(b) mixing at least one of said CO2 donor and said acidic component with said at least partially melted ingredient wherein said ingredient is present in an amount

sufficient to stabilize said at least one of said CO2 donor and said acidic component to form an at least partially molten blend in which said at least one of said CO2 donor and said acidic component is substantially dispersed,

(c) cooling said at least partially molten blend,

(d) combining said cooled at least partially molten blend, said pharmaceutically active substance and any remaining portion of said effervescent system and

(e) forming said stabilized medicament, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (); and 2) Selection of any order of mixing ingredients is prima facie obvious. (*In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)).

Robinson et al. mixes the components and then hot-melts them while Applicant merely melts one component first and then adds others to the first component. No unexpected results have been argued.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leslie et al. GB 2307857.

Applicant claims a process for producing a stabilized medicament, said stabilized medicament comprising: (A) an effervescent system comprising: (i) a CO2 donor, and (ii) an acidic component; (B) a pharmaceutically active substance, and (C) at least one ingredient selected from the group consisting of fusible sugars, sugar alcohols, and sugar substitutes, wherein said process comprises the steps of:

(a) at least partially melting said ingredient,

(b) mixing at least one of said CO2 donor and said acidic component with said at least partially melted ingredient wherein said ingredient is present in an amount sufficient to stabilize said at least one of said CO2 donor and said acidic component to form an at least partially molten blend in which said at least one of said CO2 donor and said acidic component is substantially dispersed,

(c) cooling said at least partially molten blend,

(d) combining said cooled at least partially molten blend, said pharmaceutically active substance and any remaining portion of said effervescent system and

(e) forming said stabilized medicament.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Leslie et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Leslie et al. also teach further processing the granules or agglomerates by breaking them down to give particles for example by milling which reads on comminuted (page 3).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Leslie et al. is that Leslie et al. do not expressly teach step (d) above.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method Leslie et al. by combining the cooled at least partially molten blend with the pharmaceutically active component and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (); and 2) Selection of any order of mixing ingredients is prima facie obvious. (*In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)).

Leslie et al. mixes the components and then hot-melts them while Applicant merely melts one component first and then adds others to the first component. No unexpected results have been argued.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Examiner, Art Unit 1616